Karen A. Spindler

Partner

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San Francisco



Karen Spindler is a corporate partner in the San Francisco office of Gibson Dunn where her practice focuses on advising life sciences companies and investors on a variety of intellectual property transactions. Karen represents the full spectrum of companies in the life sciences sector, including companies operating in the areas of pharmaceuticals, biologics, diagnostics, and medical devices.

Karen has considerable experience structuring complex strategic collaboration and partnering transactions, including co-development, co-commercialization and joint venture arrangements, and advising on manufacturing and supply agreements, services arrangements, and academic licenses.

In addition, Karen regularly counsels investors and operating companies on complex IP issues arising in the context of corporate transactions (including mergers, product acquisitions, product spin-outs and other structured M&A transactions), and financial investors and company sellers in royalty monetizations.

Select Representative Matters - Strategic Collaborations and Royalty Monetizations

- **Merck & Co., Inc.** in various collaboration and alliance transactions across therapeutic areas
- **Sage Therapeutics** in its (i) collaboration with Biogen for zuranolone (SAGE-217) and SAGE-324 in psychiatric and neurological disorders, valued in excess of $1.525 billion (*the fourth largest biopharma transaction of 2020*), and (ii) collaboration with Shionogi to accelerate development of SAGE-217 in key Asian markets for major depressive disorder and other indications, valued at in excess of $575 million
- **Arrowhead Pharmaceuticals** in its (i) exclusive license agreement with GlaxoSmithKline to develop and commercialize ARO-HSD, Arrowhead's Phase 1/2 RNA interference therapeutic for nonalcoholic steatohepatitis (NASH), in all territories except Greater China, with a $120 million upfront and potential milestone and royalty payments in excess of $910 million, (ii) formation of joint venture, Visirna Therapeutics, with Vivo Capital and exclusive license to Visirna to develop and commercialize certain of Arrowhead's RNA interference therapeutics for cardiometabolic diseases in Greater China, and (iii) global collaboration with Takeda to develop ARO-AAT investigational RNA interference therapy to treat alpha-1 antitrypsin-associated liver disease, with a $300 million upfront and potential milestone and royalty payments in excess of $740 million
- **Roivant Sciences** in its (i) license agreement with Eisai for exclusive worldwide rights to Eisai's anticancer splicing modulator small molecule H3B-8800, and (ii) strategic collaboration with Affimed to in-license AFM32 and access Affimed's Redirected Optimized Cell Killing (ROCK®) platform to develop and commercialize novel ICE® molecules for oncology uses, with Affimed receiving $60 million upfront

Capabilities

Life Sciences
Capital Markets
Emerging Companies / Venture Capital
Mergers and Acquisitions
Royalty Finance

Credentials

Education

Santa Clara University - 2002 Juris Doctor
Stanford University - 1996 Bachelor of Science

Admissions

California Bar

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and potential milestone and royalty payments in excess of $2 billion

- **InnoCare Pharma** in its (i) collaboration with Biogen for orelabrutinib (a BTK inhibitor), with a $125 million upfront and potential milestone and royalty payments in excess of $812.5 million, and (ii) in-license with Incyte for rights to tafasitamab (a CD19 targeting monoclonal antibody) in Greater China, with Incyte receiving $35 million upfront and potential milestone and royalty payments in excess of $82.5 million
- **Selecta Biosciences** in its (i) strategic license agreement with Takeda for applications of Selecta's ImmTOR™ platform to develop gene therapies for lysosomal storage disorders, with Selecta eligible to receive up to $1.12 billion, (ii) global agreement with Swedish Orphan Biovitrum AB for SEL-212 for the treatment of chronic refractory gout, with a $100 million upfront and potential milestone and royalty payments in excess of $630 million, and (iii) option & license agreement with Sarepta Therapeutics to develop and commercialize Selecta's ImmTOR™ platform with gene therapy candidates for Duchenne muscular dystrophy and certain limb-girdle muscular dystrophies
- **Ginkgo Bioworks** in (i) the formation of all new companies by its $350 million Ferment Consortium, including: Joyn Bio (plant microbiome), Motif FoodWorks (food ingredients), Allonnia (waste remediation), Arcaea (beauty), Ayana Bio (bioactives), and Verb Biotics (probiotics), (ii) its collaboration with Synlogic to accelerate its pipeline of Synthetic Biotic medicines using Ginkgo's cell programming platform providing an $80 million equity investment in Synlogic and a $30 million payment to Ginkgo for research and development, and (iii) its alliance with Genomatica for bio-based production of intermediate chemicals
- **Berkeley Lights** in its strategic collaboration with Thermo Fisher Scientific to accelerate and improve the development and manufacturing of stable AAV (Adeno-Associated Viral) and LV (Lentiviral) vector producer cell lines
- **Arvelle Therapeutics** in its licensing agreement with SK Biopharmaceuticals obtaining exclusive rights to develop and commercialize Cenobamate® in Europe valued up to $530 million
- **Arvinas** in agreements with Bayer to jointly launch a company to leverage Arvinas' PROTAC® technology for agricultural applications and to leverage Arvinas' novel PROTAC® protein degrader technology to develop human therapeutics in certain indications, for a value of over $110 million in cash and committed funding for the human disease collaboration, the agricultural JV, and an equity investment in Arvinas
- **Corbus Pharmaceuticals** in its strategic collaboration with Kaken Pharmaceutical granting exclusive rights to commercialize Lenabasum® in Japan for systemic sclerosis and dermatomyositis valued up to $200 million
- **Ambys Medicines** in its global strategic partnership with Takeda Pharmaceutical under which Takeda commits $100 million to pioneer development of first in class liver therapies, including participation in Ambys' Series A financing
- **Royalty Pharma** in its purchases of royalties in transactions, including (i) Blueprint Medicines' $1.25 billion strategic financing collaborations with Sixth Street and Royalty Pharma, (ii) its $240 million acquisition of the worldwide royalties for Oxlumo® from Dicerna, (iii) its up to $270 million upfront, equity and loan arrangement with Epizyme and $330 million agreement with Eisai, for the worldwide royalties to tazemetostat, (iv) its $320 million acquisition of the EU, U.K. and Swiss royalties for Crysvita® from Ultragenyx, (v) its $827 million acquisition of the worldwide royalties to Promacta® (eltrombopag) from Ligand Pharmaceuticals, (vi) synthetic royalty financings totaling more than $2 billion with BioHaven, Immunomedics, Sanofi and other confidential counterparties, and (vii) its $3.3 billion purchase of Ivacaftor® royalty rights from the Cystic Fibrosis Foundation
- **Ultragenyx** in its $500 million sale of part of U.S. royalties for Crysvita® to Omers Capital Markets

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- Other **biotech clients** on licensing foundational IP assets from universities and other academic entities

Select Representative Matters - M&A and Financings

- **Ginkgo Bioworks** in its acquisition of the assets of Project Beacon COVID-19 LLC, integrating Project Beacon's capabilities with Ginkgo's Concentric offering to support widespread COVID-19 monitoring through biosecurity and public health
- **Atara Biotherapeutics** in the sale to Fujifilm Holdings Corp. of Atara's T-cell operations and manufacturing facility for a $100 million upfront and the execution of a long-term supply agreement with Fujifilm for T-cell immunotherapy development
- **OtiTopic**, a drug development company with a late-stage inhalable, in its sale to Philip Morris International
- **Assertio Therapeutics** in a stock-for-stock merger to acquire Zyla Life Sciences
- **SentreHeart** in its sale to AtriCure for up to $300 million in upfront and earnout payments
- **Ocera Therapeutics** in its sale to Mallinckrodt in a cash tender offer, plus contingent value right
- **TPG's The Rise Fund** in connection with (i) the $145 million Series B financing of Rallybio, and (ii) the $35 million Series A of Sling Therapeutics, Inc.
- **KKR Healthcare Growth Fund** in its investment in Biosynth Carbosynth and Biosynth Carbosynth's acquisition of Vivitide
- **BVF Partners** in connection with (i) the $102 million Series B financing of Plexium, and (ii) the $40 million Series B financing of Elektrofi

**Includes matters prior to joining Gibson Dunn.*

Recognition

- Recognized by *Best Lawyers in America*® 2022-2025 as Lawyer of the Year in Biotechnology and Life Sciences (San Francisco)
- Nominated by *LMG Life Sciences* as "Licensing & Collaboration Attorney of the Year" 2021, 2022 and 2025
- "Life Sciences Star" by *Euromoney Legal Media Group* for licensing and collaboration expertise in the life sciences industry (every year since 2012)
- One of the world's leading 1000 patent practitioners by *Intellectual Asset Management (IAM)* (every year since 2012)

Before joining the firm, Karen was a partner at another international law firm for several years in its San Francisco office. Prior, she was a partner at an Am Law 100 law firm in its San Francisco and Palo Alto offices. Karen received her law degree, *magna cum laude*, from Santa Clara University School of Law, where she was a member of the Order of the Coif and Senior Production editor of the *Computer & High Technology Law Journal*. She received her B.S. in biology with honors from Stanford University.

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